

Message Text

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TO SECSTATE WASHDC 6813

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PASS F.D.A. AND AGRICULTURE FOR FAYANS

E.O. 11652: N/A

TAGS: EAGR, GW

SUBJECT: CURRENT LEGISLATIVE STATUS OF SACCHARIN IN
GERMANY

REF: STATE 063338

1. BEGIN SUMMARY. SACCHARIN IS AN APPROVED SWEETENER
FOR USE IN CERTAIN SPECIFIED FOOD PRODUCTS. THE FRG
ANNOUNCED ITS INTENTION TO MAINTAIN THE EXISTING
APPROVAL FOR USE OF SACCHARIN IN GERMANY UNTIL GERMAN
SCIENTISTS AND OFFICIALS HAVE HAD THE
OPPORTUNITY TO THOROUGHLY REVIEW THE RESULTS OF THE
RECENT CANADIAN STUDY. END SUMMARY.

2. THE USE OF SACCHARIN IN FOODS IS BASICALLY REGULATED
BY TWO ORDINANCES: A) THE ORDINANCE ON TRADE IN SACCHA-
RIN OF FEB.27, 1939 AS AMENDED. ARTICLE 5 OF THIS
ORDINANCE PROHIBITS THE ADDITION OF SACCHARIN TO FOODS
AND DRUGS AS WELL AS THE MARKETING OF FOODS AND DRUGS
CONTAINING SACCHARIN. EXEMPT FROM THIS PROHIBITION ARE
ONLY THOSE FOODS AND PRODUCTS SPECIFICALLY LISTED IN
ARTICLE 6 OF THIS ORDINANCE. FOLLOWING IS THE LIST
OF THE EXEMPTED FOODS AND PRODUCTS:
ARTIFICIALLY PRODUCED BEVERAGES AND BASE PRODUCTS
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THEREOF; VINEGAR AND ACETIC ACID; TOP FERMENTED
BEER WITH A LOW WORT CONTENT; COMMUNION OR UNLEAVENED
WAFERS ("OBLATEN"); CHEWING TOBACCO, CHEWING GUM;
DRUGS MARKETING ONLY BY PHARMACIES AND ON PRESCRIPTION
OF A PHYSICIAN; X-RAY CONTRAST MEDIA (SUCH AS E.G.
BARIUMSULFATE IN SUSPENSION); DRUGS PRIMARILY
CONTAINING COD LIVER OIL; OTHER DRUGS FOR WHICH

THE USE OF SACCHARIN IS SPECIFICALLY APPROVED BY
THE FEDERAL MINISTRY OF HEALTH.

B) THE ORDINANCE ON DIETETIC FOODS OF JUNE 20, 1963
AS AMENDED. ARTICLE 8 OF THIS ORDINANCE APPROVES
SACCHARIN (AS WELL AS CYCLAMATES) AS AN ARTIFICIAL
SWEETENER FOR DIETETIC FOODS USED FOR PURPOSES RE-
QUIRING A SUGAR SUBSTITUTE (FOODS FOR DIABETICS).
FURTHERMORE, SACCHARIN MAY BE MARKETED IN TABLET FORM,
I.E. USUALLY COMBINED WITH CYCLAMATES.

3. THE FEDERAL MINISTRY OF HEALTH ON MARCH 18 PUBLICALLY
ANNOUNCED ITS INTENTION TO MAINTAIN THE EXISTING APPRO-
VAL FOR USE OF SACCHARIN IN GERMANY. IN ITS ANNOUNCE-
MENT, FEDMINHEALTH STATED THAT DECISION WAS BASED ON
THE PRESENTLY AVAILABLE MATERIAL INCLUDING TWO RECENTLY
COMPLETED GERMAN STUDIES ON THE CARCINOGENIC EFFECT OF
SACCHARIN ON RATS. THE STUDIES REVEALED NO CARCINOGENIC
EFFECT. THE MAXIMUM LEVEL USED IN THESE STUDIES
AMOUNTED TO 1 PERCENT OF SACCHARIN IN THE FEED. TWO
ADDITIONAL GERMAN STUDIES DESIGNED TO TEST FOR ANY
POSSIBLE TERRATOGENIC AND MUTAGENIC EFFECTS OF SACCHARIN
ARE STILL UNDER WAY. PRELIMINARY FINDINGS OF THESE
STUDIES DO NOT INDICATE ANY NEGATIVE EFFECT.

4. THE GERMAN DECISION NOT TO TAKE ANY ACTION AGAINST
SACCHARIN, HOWEVER, IS PENDING THE FINAL CONCLUSIONS
DRAWN BY GERMAN SCIENTISTS AND THE FEDMIN
HEALTH AFTER DETAILED REVIEW OF THE NEW CANADIAN STUDY
ON SACCHARIN. IN DISCUSSION WITH US, FEDMINHEALTH
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OFFICIALS, HOWEVER, EXPRESSED THE FEELING THAT - BASED
ON PRELIMINARY INFORMATION MADE AVAILABLE TO THEM BY
OUR OFFICE - THE MAXIMUM QUANTITY OF SACCHARIN FED IN
THE CANADIAN STUDY WAS TOO LARGE TO ALLOW A FINAL
CONCLUSION THAT SACCHARIN IS DANGEROUS TO HUMAN HEALTH
IN THE QUANTITIES GENERALLY CONSUMED IN GERMANY.

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Copy: SINGLE
Sent Date: 25-Mar-1977 12:00:00 am
DecapTION Date: 01-Jan-1960 12:00:00 am
DecapTION Note:
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Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Source: CORE
Document Unique ID: 00
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Line Count: 103
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TAGS: EAGR, GE, US
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